K042459

NOV 17 2004

510(k) Summary
SYNCHRON LX® Systems
Hemoglobin A1c2 (HbA1c2) Reagent

1.0 **Submitted By:**

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2.0 **Date Submitted:**

September 8, 2004

3.0 **Device Name(s):**

3.1 **Proprietary Names**

SYNCHRON LX® Systems Hemoglobin A1c2 (HbA1c2) Reagent

3.2 **Classification Name**

Glycosylated hemoglobin assay (21 CFR § 864.7470)

4.0 **Predicate Device:**

Candidate	Predicate	Manufacturer	Docket Number
SYNCHRON LX Systems HbA1c2 Reagent	SYNCHRON Systems HbA1c Reagent	Beckman Coulter, Inc.	K010748

5.0 **Description:**

The SYNCHRON LX® System(s) HbA1c2 reagent is designed for optimal performance on the SYNCHRON LX® System(s). The reagent kit contains two A1c2 80-test cartridges, one Hb2 160-test cartridge and one

2 mL bottle each of Hb/A1c2 Calibrator Level 2, A1c2 Calibrator Levels 3, 4 and 5.

6.0 Intended Use:

The Hemoglobin A1c2 (HbA1c2) reagent kit, when used in conjunction with SYNCHRON LX® System(s) and SYNCHRON® Systems HbA1c2 Calibrators, is intended for the quantitative determination of hemoglobin A1c (HbA1c2) concentration as a percentage of total hemoglobin in human whole blood.

7.0 Comparison to Predicate(s):

The following tables show similarities and differences between the predicate identified in Section 4.0 of this summary.

Similarities to the Predicate

Reagent	Aspect/Characteristic	Comments
HbA1c2 Reagent	Intended Use	Same as Beckman SYNCHRON HbA1c Reagent
	Liquid Stable Reagent	
	Analytical Range	
	Sample Type	
	Reference Intervals	
	Shelf Life Stability	
	Anticoagulants Used	
	Storage Temperature (+2°C to +8°C)	
	Interferences	
	Specificity	
	Sensitivity	
	Sample Size	
	Methodology	
	Formulation	
	Calibration	

Differences From The Predicate

Reagent	Aspect/ Characteristic	Comments
HbA1c2 Reagent	Sample Preparation	HbA1c2 does not require any sample preparation whereas HbA1c requires manual (off-line) sample preparation; the system automatically prepares the sample (on-line). However, HbA1c2 can be prepared off-line as well.
	Limitations	Additional limitations have been added to the HBA1c2 assay that relate to Erythrocyte Sedimentation Rate and proper mixing of whole blood.
	Reactive Ingredients	HbA1c2 contains Hemolyzing Reagent in the reagent cartridge itself whereas HbA1c reagent required a customer to hemolyze a sample off-line with separately purchased Hemolyzing Reagent.

8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison, stability, linearity, and imprecision experiments.

Method Comparison Study Results

Instrument	Slope	Intercept	r	n	Comparison Method
SYNCHRON LX	0.911	0.46	0.991	80	SYNCHRON HbA1c
SYNCHRON LX	1.042	-0.56	0.994	80	Tosoh A1c

SYNCHRON LX System HbA1c2 Reagent Imprecision Results

Sample	Mean (%)	S.D. (%)	%C.V.	N
Within-Run Imprecision				
Normal	5.5	0.07	1.2	80
Abnormal	9.8	0.09	1.0	80
Total Imprecision				
Normal	5.5	0.14	2.6	80
Abnormal	9.8	0.27	2.8	80

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 17 2004

Ms. Kim Walker
Regulatory Affairs Manager
Beckman Coulter, Inc.
200 S. Kraemer Boulevard
P.O. Box 8000
Brea, CA 92822-8000

Re: k042459
Trade/Device Name: SYNCHRON LX® Systems Hemoglobin A1c2 (HbA1c2) Reagent
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: LCP
Dated: September 8, 2004
Received: September 10, 2004

Dear Ms. Walker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Cornelia B. Rooks

Cornelia B. Rooks, MA
Acting Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **k042459**

Device Name: **SYNCHRON LX® Systems Hemoglobin A1c2 (HbA1c2) Reagent**

Indications for Use:

The Hemoglobin A1c2 (HbA1c2) reagent kit, when used in conjunction with SYNCHRON LX® System(s) and SYNCHRON® Systems HbA1c2 Calibrators, is intended for the quantitative determination of hemoglobin A1c (HbA1c2) concentration as a percentage of total hemoglobin in human whole blood.

Measurement of hemoglobin A1c is accepted as a method to measure long-term glucose control in patients with diabetes mellitus (a chronic disorder associated with disturbances in carbohydrate, fat, and protein metabolism and characterized by hyperglycemia). Determination of hemoglobin A1c provides an important diagnostic tool for monitoring the efficiency of dietary control and therapy during treatment of diabetes mellitus.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

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Office of In Vitro Diagnostic
Device Evaluation and Safety

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